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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,221	07/27/2006	Alvin Janski	KEDI 8828 W1	6469
1688 7590 02/01/2011 Polster, Lieder, Woodruff & Lucchesi, L.C. 12412 Powerscourt Dr. Suite 200 St. Louis, MO 63131-3615				
EXAMINER NATNITHITHADHA, NAVIN				
ART UNIT 3735		PAPER NUMBER		
MAIL DATE 02/01/2011		DELIVERY MODE PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/588,221

**Applicant(s)**

JANSKI ET AL.

**Examiner**

NAVIN NATNITHADHA

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-11, 13-15 and 18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11, 13-15 and 18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 20060727
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Response to Preliminary Amendment***

1. According to the Amendment, filed 27 July 2006, the status of the claims is as follows:

Claims 1, 4, 6, 8-10, 13, and 15 are currently amended;

Claims 5, 7, 11, 14, and 18 are as originally filed; and

Claims 2, 3, 12, 16, and 17 are cancelled.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1 and 4-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim(s) 1 and 4-11 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these claims are method or process claims that do not transform underlying subject matter (such as an article or materials) to a different state or thing, nor are they tied to a particular machine. *See Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). *See also In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008), where the Fed. Cir. held that method

claims must pass the "machine-or-transformation test" in order to be eligible for patent protection under 35 USC 101.

Examiner suggest inserting language directed to a particular machine, such as using a computer or micro-processor (see Specification, pp. 14-15), that imposes a meaningful limit on the claim's scope, i.e. a machine that involve more than a field of use limitation and involve more than insignificant extra-solution activity.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 5, 13, 14, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Seidman, U.S. Patent No. 6,416,479 B1 ("Seidman").

**As to Claims 1 and 13**, Seidman teaches the following:

A method for predicting the onset of a medical condition in a human patient (see Abstract), comprising:

measuring concentration levels of at least one breath gas exhaled by the patient over a period of time (see col. 6, l. 62, to col. 7, l. 23);

comparing said measured concentration levels with predetermined concentration levels indicative of an onset of said medical condition, wherein said medical condition is

selected from a set of medical conditions including pain (“...severity of various pathological conditions in pregnancy including... premature uterine contractions...”, which is a type of pain, see Abstract) and the occurrence of a stroke.

**As to Claim 4**, Seidman teaches the following:

generating a profile responsive to said measured concentration levels, said profile representative of a likelihood of onset for said medical condition (see col. 9, l. 33, to col. 10, l. 32).

**As to Claims 5 and 18**, Seidman teaches the following:

measuring a concentration of carbon monoxide breath gas exhaled by the patient (see col. 6, l. 62, to col. 7, l. 23).

**As to Claim 14**, Phillips teaches the following:

wherein said means for comparing includes a logic circuit (see col. 7, ll. 16-24).

#### ***Allowable Subject Matter***

4. Claim 15 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 6-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office Action.
6. The following is a statement of reasons for the indication of allowable subject matter:

Braun, U.S. Patent No. 7,101,340 B1, teaches a medical diagnostic device for analyzing gases in expired breath comprising a computer that compares a measured patient's breath profile to the stored database of spectroscopic breath profiles and that provides diagnosis of the presence or absence of a medical condition.

Lin et al, U.S. Patent No. 6,712,770 B2, teaches a multi-sensor array to detect specific volatile organic chemicals (VOC) in the breath. The multi-sensor array carries a substance that is reactive to the VOC as a sensory receptor. The data collected is compared with a database for a variety of disorders to diagnose disorders or physiological state. The database is built up by statistically analyzed data for the disorders.

**As to Claims 6-11**, the prior art of record does not teach the method for predicting the onset of a medical condition in a human patient of claims 6 and 9, including the combination of the following:

measuring a concentration level of at least one breath gas exhaled by the patient over a period of time; and

comparing said measured concentration levels with a predetermined concentration profile indicative of an onset of at least one sickle-cell pathology, or indicative of an onset of at least one selected (NO)-related negative influence, wherein said at least one selected (NO)-related negative influence is associated with an ivHb-dependent decrease in (NO) bioavailability.

**As to Claim 15**, the prior art of record does not teach the apparatus for predicting the onset of a medical condition in a human patient of claim 13, including the

following: a display operatively coupled to said means for comparing; wherein said means for comparing is further configured to generate an profile responsive to said measured concentration level levels, said profile representative of a likelihood of onset for said medical condition; and wherein said means for comparing is further configured to control said display to display said profile.

### ***Conclusion***

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Patent Examiner, Art Unit 3735  
01/31/2011